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EXAMINER

GORDON, BRIAN R

ART UNIT PAPER NUMBER

1743

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicati n N .	Applicant(s)
	09/931,138	DALKIDIS ET AL.
	Examiner	Art Unit
	Brian R. Gordon	1743

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --  
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 16 August 2001 .

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-19,23,24,27 and 28 is/are rejected.

7) Claim(s) 20-22,25,26 and 29 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 16 August 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_ .

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Specification***

2. The disclosure is objected to because of the following informalities: On page 5, line 7, references are made to the claims. The claims are interpreted in light of the specification not vice versa. As such, the specific references to the claims should be corrected.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 10, 13-14, 16-19, 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ljungmann, US 6,017,495.

Ljungmann discloses a staining apparatus for staining of tissue specimens placed on microscope slides comprises a number of staining stations (4) and other working stations (1, 2, 3), where the staining stations (4) receive vessels (5) having liquid baths for receiving baskets containing microscope slides with the topical specimens, and a transport mechanism (17-20) having a hoisting device (17) arranged

to be moved over the vessels (5) and to place baskets in or take these up from the vessels, and to transfer the baskets between the working stations (1-4) in accordance with a programme-controlled staining process.

Ljungmann teaches that in microscopic examination of cell and tissue specimens it is necessary with a preparation of the specimens in accordance with certain mutually dependent working steps. After fixation and embedment of the specimens, the specimen blocks must be cut. In order to enable an easy microscopic examination, the embedment medium must be removed, and thereafter the specimens are stained.

The staining apparatus shown in FIG. 1 is constructed to be able to carry out all types of routine and special staining processes within the field of **histology and cytology**. In the illustrated embodiment the apparatus includes 36 working stations, but this number can be increased, for example to 50 stations. The stations may e.g. comprise four to five fetching/unloading stations, **four to five waiting/stove stations (heatable reagent stations)**, four to five water rinsing stations and twenty to thirty staining stations. In FIG. 1, said station types--in the above-mentioned order--is designated by the reference numerals 1, 2, 3 and 4. Each of the staining stations 4 receives a container or vessel 5 having a dyeing bath 6 (see FIG. 2) for the reception of baskets 7 containing microscope slides with the topical tissue specimens. In a corresponding manner vessels 8 for input and output of baskets are arranged at the fetching/unloading stations 1, and on the rinsing stations 3 there are arranged suitable containers or vessels 9 for rinsing water baths.

As shown, the waiting/stove stations 2 are shaped as an upwardly open casing 14 (**holder**) having an upper edge for the support of slide baskets 7 in a number of stove positions corresponding to the individual stations. The stations are heated by means of hot air supplied from a fan 15 in combination with a heating element (not shown).

The electronic units, which are based on microprocessor technology, controls the operation of the apparatus in accordance with the topical programme. The apparatus has a memory (EEPROM) in which there may be stored up to 32 different programmes. Up to three different programmes can be in operation simultaneously. The electronic units give the possibility for print-out of staining or dyeing programme and baths conditions. Further, there is a possibility for automatic warning of dyeing bath conditions.

It is also disclosed that the containers may be made of a transparent material, e.g. glass (thermally conductive).

5. Claims 1-3, 6-7, 13-14, 17-19, 23-24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ljungmann et al. 6,436,348.

Ljungmann et al. disclose a staining apparatus for preparation of tissue specimens placed on microscope slides, comprising a plurality of stations in the form of vessels having liquid baths for receiving baskets or suspensions receiving microscope slides with the topical specimens, a device for transporting each of the baskets/suspensions to respective stations to undergo a staining process, and a control unit for controlling the staining process in accordance with a chosen program. The

apparatus is provided with a magazine for loading and simultaneous reception of a chosen number of baskets/suspensions with microscope slides, the magazine being provided with a device for heating of the baskets/suspensions placed in the magazine (**heatable reagent station**).

By providing the staining apparatus with a magazine which can receive several baskets having associated individual programs at the same time, and which is provided with a heating means for obtaining as quickly as possible a desired temperature to melt down the embedment medium on the histological specimens, there is achieved that one does not need a separate process for preheating and melting down the embedment medium in a separate stove. This implies a substantial work and time saving, since otherwise one has to load the baskets one by one with intervals of several minutes before the apparatus can take care of the individual baskets.

The magazine has a heating chamber which is arranged such that the transport means is allowed to fetch the topical basket directly from the chamber in accordance with a given temperature and a given minimum time in compliance with different programs which also control the different steps of the basket in the process wherein removal of the embedment medium, staining of the tissue specimens and delivery of the basket take place.

In accordance with the invention the apparatus comprises a magazine for loading and simultaneous reception of a chosen number of baskets/suspensions with microscope slides. In the shown embodiment the magazine comprises a magazine housing 11 (**holder with a recess for insertion of the magazine**) in which there is

arranged a framework 12 for the support of baskets/suspensions 3. As appears from FIG. 2, the magazine in the shown embodiment can receive maximum five baskets. In the magazine housing there is arranged a heating means comprising a heating element 13 and a fan 14, where the fan is arranged to blow hot air towards baskets/suspensions placed in the magazine, for heating of these to a desired temperature. The heating means appropriately is arranged to be controlled by the control unit in accordance with the topical program.

From FIGS. 4 and 5 it further appears that the magazine is provided with a lid 20 which is opened at the initial loading of baskets/suspensions with microscope slides. The baskets 2 and the magazine housing 11 are supported by a positioning or carrier plate 21 (**pan**) which is provided with adapted holes (**means for receiving holder**) for receiving the baskets and the magazine housing, these being provided with outwards projecting flange portions (suggested for the magazine housing in FIGS. 2, 4 and 5) supported by the plate. A bottom box 22 is arranged beneath the carrier plate 21, for collection of liquid which may possibly come from the baths in the vessels or drip from baskets during transport thereof. Over the stations with the vessels 2 there is further shown to be arranged a bipartite lid 23 for access to the chemicals in the vessels.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 7, 11-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungmann et al. or Ljungmann as applied to claims 6 and 14 above, and further in view of Titcomb et al. US 6,004,512.

Ljungmann et al. or Ljungmann does not disclose that the device comprises metal or insulation.

Titcomb et al. discloses a sample cartridge slide block with a temperature controller for heating microscope slides. The block is made from material having a relatively high thermal conductivity. Typically metals such as aluminum, copper, or

silver are used in the plates. If plates are to be contacted with an electrically conductive surface, the plates preferably have an electrically insulative coating disposed thereover.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a highly conductive metal material as taught by Titcomb et al. within the heating devices of Ljungamann et al. and Ljungman to obtain uniform heating of the slides within the heating station.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungmann et al. or Ljungmann as applied to claim 7 above, and further in view of Chu US 5,958,341.

Ljungmann et al. or Ljungmann does not disclose that the device comprises plastic.

Chu discloses slideholders which are useful for processing tissue samples on microscope slides are described. These slideholders hold multiple slides and are designed in conjunction with specialized trays for rapidly processing the mounted tissue samples such as for immunocytochemical staining. The slide holder consists of two plastic portions with ridges wherein one portion is placed onto each side of the slides and then clipped together such that the slides are held between the two portions of the slideholder. The ridges properly align and space the slides. In one variation of this and other embodiments, the slideholder has ribbed surfaces of plastic or rubber which help to hold the slides firmly in place.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ljungmann et al. or Ljungmann by incorporation the

plastic portions as taught by Chu in order to hold the slides firmly in place during processing or transporting.

11. Claims 7-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljungmann et al. or Ljungmann as applied to claim 6 above, and further in view of Richards et al. US 6,296,809.

Ljungmann et al. or Ljungmann does not disclose that the device comprises plastic, metal, or ceramic material.

Richards discloses an apparatus for automatically staining or treating multiple tissue samples mounted on microscope slides. Individualized slide temperature control is accomplished by the heating system that has thermal platforms radially mounted to the carousel for heating the slides and sensing the temperature of each. The heating system also permits automated de-waxing if necessary.

It is a particular feature of the invention that adjacent slides may optionally be heated to different temperatures at particular points in time. This is accomplished by making the slides thermally isolated from one another by having high thermal resistance between the heaters. As one skilled in the art will readily appreciate, thermal resistance is a function of the conductivity of the material, the thickness of the material, and the distance the heat must travel. Hence, a variety of materials may be employed to thermally isolate adjacent slides including rubber, plastics, ceramics, or metals for they provide thermal resistance.

In a preferred embodiment, mounted about the perimeter of plate 60 and depending perpendicularly from the underside thereof is a skirt 62 preferably

constructed of rubber or a similar material that is both waterproof and a thermal insulator. The insulative properties of skirt 62 helps to facilitate these temperature differentials between adjacent slides. It should be appreciated that a variety of materials may be employed in lieu of rubber to thermally insulate adjacent slides including ceramics and plastics that can withstand temperatures of at least 100.degree. C. Also, the components housed within the cavity of heater/sensor unit 58 must be shielded from the various heated solutions (oil and water based) that will be applied during the staining operation of the apparatus.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Ljungmann et al. or Ljungmann by incorporating the plastic, metal, or ceramic material as taught by Richards in order to provide a container with the proper thermal resistance.

***Allowable Subject Matter***

12. Claims 20-22, 25-26, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor suggest a device comprising a heating device in the form of an electrical heating plate integrated into the holder, a holder configured to receive two or more containers, or a heating plate included in the in contact with the base planar surface.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards et al., Richards et al., Meikle, Bogen et al. (,963; ,061), Keefe, Tabata, Pedersen, Muck et al., Wilkie et al., Howells et al., Muller et al., Williamson et al., Revesz, Henkin, and Clarke disclose heating devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg  
May 19, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700